

### REMARKS

Claims 9, 10, 12, 13, 16, 17, 24 - 40 are pending.

Claims 9, 16, 17, and 26 have been amended to remove the term “fragments” in order to comply with antecedent basis requirements, as claim 28 from which they depend does not recite this language. Claim 29 has been rewritten in independent form. This is believed to render the rejection of claim 29 moot. New claims 30 – 37 are supported by the original claims and throughout the specification. New claims 38 - 40 are supported in the specification, e.g., at page 62, lines 15-17, page 48, lines 24, and by the original claims.

No new matter is added by this amendment.

- I. Claims 12, 13 and claim 28 are rejected under 35 USC 102(b) as being anticipated by Horwitz, US Patent No. 5,108,745 (the '745 patent).*

Applicants respectfully traverse this rejection.

The Examiner has stated that the Declaration of Peter Andersen was not persuasive because it was insufficient to overcome the presumption of validity of the Horwitz, US Patent No. 5,108,745. However, applicant submits that the Declaration is sufficient to establish what one of skill in the art would have understood from reading of Horwitz. It is for this purpose that the Declaration should be considered.

In the prior Office Action the examiner has stated that the extracellular products of the present invention read on this disclosure of Horwitz and the examiner invited applicants to supply evidence to the contrary. Having supplied this evidence, the examiner has refused the Declaration as not being sufficient to overcome the presumption of validity of Horwitz, US Patent No. 5,108,745.

However, applicants' goal was not to invalid the patent on the basis of inoperativeness or lack of written description. The intent of the Declaration was to establish that the products referenced by Horwitz are secreted products and are in fact very different from the components recited in the present invention. For this purpose, the Declaration should be sufficient.

Reconsideration of the Rule 132 Declaration and the discussion in Rule 116 Amendment submitted February 9, 2009 are requested.

Further, the claims require at least one other element not taught by Horwitz, a point which has heretofore been ignored. More particularly, Horwitz contains no teaching of the use of a polymeric carrier for any Mycobacterium polypeptide.


For all of these reasons, Horwitz does not teach or suggest the present invention.

Claims 9, 10, 12, 13, 16, 17, 24-27 were rejected under 35 USC 112, first paragraph. The amendment of claims 9, 16, 17, and 26 is believed to render the outstanding rejection moot.

Reconsideration and withdrawal of the rejection is requested.

Please charge any deficiency in any fee to deposit account number 08-3040.

Respectfully Submitted,  
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